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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,649

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Eric Abel

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,649	<b>Applicant(s)</b> ABEL ET AL.	
	<b>Examiner</b> LINDSEY BACHMAN	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1-14 and 18-42 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1-14 and 18-42 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 20 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

This Office Action is in response to Applicant's amendment filed 7 September 2010 in light of the RCE filed 4 November 2010.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 September 2010 has been entered in light of the RCE filed 4 November 2010.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, an inflatable element that moves the arms from a collapsed to expanded position, as recited in claim 27; each arm being coupled with at least one or two expandable elements, recited in claims 29 and 30; and the cover, recited in claim 31, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 27 recites that an inflatable element moves the apparatus into the expansion position. Although the specification describes the use of an expandable

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member at paragraphs [0109]-[0119] and Figures 52-81, it does not describe the use of an inflatable member that moves the expandable arms from the collapsed position to the expandable position.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-4, 8, 9, 14, 18-23, 26, 31, 34, 35, 37, 41 and 42 rejected under 35**

**U.S.C. 102(a and e) as being anticipated by Beland et al. (US Patent 6,443,959).**

Claim 1, 14, 18: Beland'959 teaches a medical apparatus that contains a guide member (3, Figure 4) defining a leading end (7) and an aperture (11) in the guide member that defines an area for access from the apparatus into a body passage. Part of the area (11) is spaced from the leading end (7) (Figure 3). The apparatus contains a pair of expansion arms (17) that extend along the edge portions of the aperture (See Figures 1 and 2, for example) and move between the expanded and collapsed configuration (Figure 1 shows collapsed configuration; Figures 2 and 5 show expanded

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configuration) by controllably expanding the expansion arms (with handles 25, 27). The arms are uninterruptedly separated by the access area (Figure 1, 2, 5)

Claim 2, 3: The arms in the Beland'959 device are capable of moving in incremental steps between a fully expanded and fully collapsed position.

Claim 4: Since the structure of the device disclosed by Beland'959 and the claimed invention is the same, it is capable of use in transanal endoscopic microsurgery.

Claim 8, 26, 42: Beland'959 discloses an activating member (15, 27) used for moving the arms between the expanded and collapsed positions. The arms move simultaneously.

Claim 9: The activating member (15, 27) is movable relative to the remainder of the apparatus (the part of the apparatus shown in Figure 3 is movable relative to the part of the apparatus shown in Figure 4).

Claim 19: The access area (11) is an elongate opening (see Figures 1, 2, 5).

Claim 20: The access area (11) is an opening extending around at least half of a perimeter of the guide member (see Figure 4).

Claim 21: Beland'959 discloses an inlet (5) at a trailing end of the device for access into the apparatus and the access area (column 3, lines 60-62).

Claim 22: The pair of expansion arms (17) are mounted on and extend longitudinally with respect to the guide member (3) (see Figure 1).

Claim 23: The expansion arms have a curved shape when in the expanded position (Figures 2, 5).

Claim 31: The portion of guide member (3) that surrounds aperture (11) may serve as a cover.

Claim 34: Beland'959 discloses a method of providing access to a body passage that includes inserting a medical apparatus (1) having a guide member (3; Figure 4) with an aperture (11) defining an access area with at least part of the access area spaced from the leading end of the apparatus (Figure 4) at least partly into a body passage with the apparatus in a collapsed condition (column 3, lines 10-16); controllably moving the apparatus from the collapsed position to an expansion position by controllably, elastically deforming a pair of expansion arms (17) extending across the edge regions of the aperture to expand the body passage in the region of the aperture (column 4, lines 23-51) and accessing the body passage through the access area spaced from the leading end of the apparatus (column 5, lines 37-40).

Claim 35: Beland'959 teaches that the step of exerting an expansion force to move the apparatus to the expansion position (column 4, lines 25-32, 39-44).

Claim 37: Beland'959 teaches controllably moving the apparatus from the expansion position to the collapsed position and removing the apparatus from the body passage (column 4, lines 49-51).

Claim 41: Beland'959 teaches performing a diagnostic procedure on the body passage (column 1, lines 48-55).

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 5-7, 12, 24, 25 and 38-40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beland'959.**

Claims 5, 6, 7: Beland'959 discloses the claimed invention except for the arms being at rest in the expanded state, versus being at rest in the unexpanded state or the arms being stressed in the collapsed state and more stressed in the expanded state. It would have been an obvious matter of design choice to make the expanded state the resting position of the arms, since applicant has not disclosed that choosing one state over the other for the resting state solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the resting state being the unexpanded state. Furthermore, if the expanded state were used as a resting state, it would have been obvious to provide a collapse force in the device in order to insert it into a body cavity and then release the collapse force to expand the device inside the body cavity.

Claim 12: It is old and well known to motorize movements that were previously controlled by hand. Further, Beland'959 teaches that it is known to use a non-manual system for controlling the activating member (column 5, lines 63-67).

Claim 24, 25: Beland'959 discloses the claimed invention except for shape memory alloy material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use shape memory alloy material, since it has



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been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

Claims 38, 39: Beland'959 teaches the limitations of claims 38 and 39 except for rotating the apparatus within the body passage.

Beland'959 states that the device only expands to one side (column 5, lines 27-33). It would be obvious to rotate the apparatus in the collapsed position to access a part of the body that is not on the side that the apparatus opens towards when initially placed in the body.

Claim 40: Although Beland'959 does not specifically disclose viewing the body through the access area, Beland'959 does teach the use of the apparatus as part of a laparoscopic procedure. It is well known that laparoscopic procedures involve viewing the body. In light of this, it would have been obvious to view the body through the passage in this procedure, as well.

**Claim 10, 13, 32, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beland'959, as applied to claim 1, further in view of Bonutti (US Patent 5,454,365).**

Claim 10: Beland'959 teaches the limitations of claim 10, including that the device is intended for use as a retractor device. Beland'959 does not teach that the dilator is actuated with a screw mechanism.

Bonutti'365 teaches a retractor device (Figures 1 and 2) that has an activating device that contains a screw mechanism with a screw threaded member (12) and

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activating member (16) and movement of the threaded member relative to the activating member adapted to move the apparatus between the expanded and collapsed positions. It would have been obvious to one of ordinary skill in the art to modify the device taught by Beland'959 with a ratchet mechanism, as taught by Bonutti'365, to controllably expand the dilator.

Claim 13: Beland'959 teaches the limitations of claim 13, including that the device is intended for use as a retractor device. Beland'959 does not teach a lock to lock the apparatus in a desired position.

Bonutti'365 teaches a retractor device that contains a lock for locking the retractor arms (62) in a particular position (column 9, lines 8-10). It would have been obvious to one of ordinary skill in the art to modify the device taught by Beland'959 with a lock, as taught by Bonutti'365, in order to lock the arms in a desired position.

Claim 32, 33: Beland'959 teaches the limitations of claim 32, including that the device is intended for use as a retractor device. Beland'959 does not teach providing force feedback to an operator when the arms are between the collapsed and expanded positions.

Bonutti'365 teaches a retractor device in which it is known to provide force feedback during movement of arms (62) between the expanded and collapsed positions (193; column 9, lines 36-47). It would have been obvious to one of ordinary skill in the art to modify the device taught by Beland'959 with a mechanism to provide force-feedback, as taught by Bonutti'365, in order to monitor and control the amount of force provided by the expansion arms.

Claim 36: Beland'959 teaches the step of exerting a collapse force on the apparatus to move the apparatus to the collapsed position (column 4, lines 33-38, 48-51). Beland'959 does not teach restraining the apparatus in the collapsed position. Further, Beland'959 does not teach that the device is biased to the expansion position.

Bonutti'365 teaches a retractor device that contains a lock for locking the retractor arms (62) in a particular position (column 9, lines 8-10). It would have been obvious to one of ordinary skill in the art to modify the device taught by Beland'959 with a lock, as taught by Bonutti'365, in order to lock the arms in a desired position.

Regarding limitation that the arms are biased to the expansion position, it would have been an obvious matter of design choice to make the expanded state the resting position of the arms, since applicant has not disclosed that choosing one state over the other for the resting state solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the resting state being the unexpanded state. Furthermore, if the expanded state were used as a resting state, it would have been obvious to provide a collapse force in the device in order to insert it into a body cavity and then release the collapse force to expand the device inside the body cavity.

**Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beland'959, as applied to claim 9, further in view of Adams et al. (US Patent 5,325,848).**

Beland'959 does not teach that the arms are actuated with a ratchet mechanism.

Adams'848 teaches a device containing expandable arms (81) (Figure 1) that are expanded with an actuating device (handle 60) including a ratchet mechanism having a slider (100) coupled to the activating member and a locking member (90). Movement of the slider (100) relative to the locking member moves the apparatus between the expanded and collapsed state (Figures 2-4). It would have been obvious to one of ordinary skill in the art to modify the device taught by Beland'959 with a ratchet mechanism, as taught by Adams'848, to controllably expand the arms.

**Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beland'959, as applied to claim 1, further in view of Shaw et al. (US Patent 5,678,572).**

Beland'959 teaches the limitations of claim 27, except for an expandable member that moves the expandable arms between the collapsed and expanded positions.

Shaw'572 teaches that it is known to move expandable arms with a sliding mechanism, as in Beland'959, or with an inflatable element (column 2, lines 57-62). The claim would have been obvious because the substitution of known expansion mechanism (sliding mechanism) for another (inflatable element) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

**Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beland'959, as applied to claim 1, further in view of Nobles et al., (US Patent Application 2002/0013601).**

Beland'959 teaches the limitations of Claims 28-30 except for a plurality of inflatable elements.

Nobles'601 teaches a cavity enlarger apparatus which comprises two annular inflatable chambers (104, 106) spaced axially on either side of a central cylindrical access area (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inflatable chambers of Nobles in the device of Shaw in order to provide additional securing means to hold the device in place.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 271-272-6208. The examiner can normally be reached Monday through Thursday from 7:30am to 4:00pm and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Gary Jackson, at 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700\_Workgroup\_D\_Inquiries@uspto.gov.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

Examiner, Art Unit 3734

/Gary Jackson/

Supervisory Patent Examiner, Art Unit 3734

September 11, 2011